REMARKS

Favorable reconsideration of this application is requested in view of the above amendments and the following remarks. Claims 20, 21, 23-26, 28, 29, 31, and 32 are pending. The claims have been revised editorially.

Claims 20, 21, 23-26, 28, 29, 31 and 32 were rejected as obvious over Depui in view of Khankari. Claims 20, 21, 23-26, 28, 29, 31 and 32 also were rejected as obvious over Depui in view of Khankari and Makino. Although the statement of the rejection identifies Makino as EP 0553777A2, from the discussion in the body of the rejection it appears that US 5,026,560 is being used. Applicants respectfully traverse these rejections.

The Office Action recognizes that Depui does not teach the percent substitution of the hydroxypropyl group required by the present claims. The Office Action further contends that the substitution should be considered similar because Depui teaches a fast disintegrating tablet having disintegrating times similar to those of the present invention. Applicants respectfully contend that the Office Action's reasoning is flawed.

As explained in materials submitted previously, the low substitution materials of the present claims were not available commercially at the time of the Depui work. As Depui provides no particular discussion of the materials or their preparation, it is clear that the materials considered by the reference were the low substitution materials commercially available from Shin-Etsu, the sole supplier of such materials. Again, the December 6, 2001 Declaration of Mr Watanabe confirmed that the 5-7% materials would not have been available at the time of Depui, which is further supported by the attached excerpts from the second (1994) and third (2000) editions of the Handbook of Pharmaceutical Excipients. Note that in the second edition, L-HPC is included as a grade of HPC (page 227). In the third edition, hydroxypropyl cellulose, low-substituted is included as a separate entity.

While Depui refers to disintegration properties, it is clear that the reference is not concerned with the buccal dissolution that is the property identified in the present claims. Depui provides a formulation that disintegrates when exposed to a relatively large volume of aqueous liquid, thereby allowing the disintegrated formulation to be consumed by the patient by drinking. This is unrelated to buccal conditions. This point is demonstrated in the Declaration of Dr. Shimizu filed herewith. Note that the formulations according to Depui, which were prepared using the lowest substituted materials that would have been expected to be available to Depui,

showed disintegration times in aqueous liquid that are consistent with the times reported in the reference. However, the disintegration under buccal conditions was unsatisfactory and did not approach the times required in the present independent claims. In contrast, the low substituted material required by the present claims provided a product that disintegrated readily under buccal conditions. This is consistent with the results reported in Dr. Shimizu's earlier Declaration of April 6, 2001. Nothing in the art of record suggests that this advantage could be obtained. Note that since orally disintegrable tablets may be administered without water, the improvement of the feeling of the product in the mouth is significant for patient compliance. Thus, the sensory evaluation of the feeling in the mouth is relevant, and this property has been recognized, for example in the Chem. Pharm. Bull. Reference filed herewith.

Note also that the Experiment 2 in the present Declaration of Dr. Shimizu included experiments where mannitol was included in a composition according to Depui. The resulting product still showed unsatisfactory disintegration in buccal conditions. Thus, the present invention exhibits properties that could not be expected even if the disclosures of Depui and Khankari are combined in the manner suggested by the rejections.

Makino does not remedy the deficiencies of Depui and Khankari. Makino discloses that a relatively broad range of hydroxypropylcellulose materials can be included in spherical granules. The reference does not identify any materials required by the present invention as being particularly useful, and the reference uses 10-13% substituted materials in its examples. Nor does the reference suggest that its use of the materials would be of benefit in improving the buccal disintegration of a tablet. The reference's use of the hydroxypropylcellulose in the spherical granules is not related to the use of the specific materials of the present claims in promoting the buccal disintegration of tablets.

In view of the above, Applicants request reconsideration of the application in the form of a Notice of Allowance.

Respectfully submitted,

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